

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Depui et al.  
Serial No : TBA  
Filed : TBA  
For : ORAL PHARMACEUTICAL DOSAGE  
FORMS COMPRISING A PROTON  
PUMP INHIBITOR AND A NSAID  
Examiner :  
Group Art Unit : 1615

<p>"Express Mail" Label No. <u>ET537319873US</u></p> <p>Date of Deposit <b><u>JULY 14, 2003</u></b></p> <p>I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to: MAIL STOP PATENT APPLICATION; Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p><u>BERNARD MAYS</u></p> <p>(Type or print name of person mailing paper or fee)</p> <p><u>Bernard Mays</u></p> <table><tr><td>Signature</td><td>Date of Signature</td></tr></table>	Signature	Date of Signature
Signature	Date of Signature	

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicants submit this communication in compliance with 37 C.F.R. §§1.56, 1.97 and 1.98.

The referenced application is a continuation of U.S. Patent Application Serial No. 10/090,882 (the “’882 application”), filed March 4, 2002, which is a continuation of U.S. Patent Application Serial No. 09/471,958, filed December 23, 1999 (the “’958 application”), now US 6,365,184, issued April 2, 2002, which is a continuation of U.S. Patent Application Serial No. 08/793,078, filed February 13, 1997 (the “’078 application”), abandoned, which was the National Stage of International Application No. PCT/SE96/01735, filed December 20, 1996.

The documents identified on the attached form PTO-1449 include the patents, publications and other information which were previously cited by or submitted to the Office in the great-grandparent ‘078 application, the grandparent ‘958 application, and the parent ‘882 application. Pursuant to C.F.R. §1.98(d), copies of the identified documents are not required in connection with this Information Disclosure Statement as copies were submitted or cited in the preceding ‘078, ‘958, and ‘882 applications and the present continuation application relies upon the earlier filing dates of the ‘078, ‘958, and ‘882 applications under 35 U.S.C. §120.

#### **TIME OF TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement transmitted herewith is being filed concurrently with a continuation application.

Applicants submit that no fee is required in connection with this submission. However, if any fee is due in connection with the communication, authorization is hereby given to charge Account No. 23-1703.

Dated: July 14, 2003

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John M. Genova", is written over a horizontal line.

John M. Genova  
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FORM PTO-1449 (REV. 2-82) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT  BY APPLICANT	Atty. Docket No. <b>1103326-0250</b>	Serial No. <b>TBA</b>
	Applicant: <b>Depui, et al.</b>	
	Filing Date: TBA	Group: 1615

### UNITED STATES PATENT DOCUMENTS

*Examiner Initial	Document No.	Date	Name	Class	Sub-Class	Filing Date, if Appropriate
	4 7 8 6 5 0 5	11-88	Lovgren et al.	424	468	
	5 4 1 7 9 8 0	05/23/95	Goldman et al.	424	464	

### FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-Class	Translation Yes   No
	0 0 7 2 0 2 1	08/82	EP			
	8 5 0 1 2 0 7	09/84	WO			
	0 5 8 7 2 2 0	08/93	EP			
	0 5 4 1 3 6 9	11/92	EP			
	2 2 8 5 9 8 9	01/95	GB			
	9 4 0 3 1 6 0	07/93	WO			
	0 6 4 8 4 8 7	10/94	EP			
	0 1 0 8 5 0 4	10/83	EP			
	8 5 0 3 4 3 6	02/85	WO			
	2 0 6 6 0 7 0	12/80	GB			
	2 1 3 2 8 8 7	11/83	GB			

### OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

	McCarthy, D.M. 1989 Gastroenterology 96:662-674, "Nonsteroidal Antiinflammatory Drug-Induced Ulcers..."
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Examiner:

Date Considered:

\* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	5 7 5 3 2 6 5	05/19/88	Bergstrand et al	424	474	

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	0 1 1 1 0 3	10/83	EP			
	0 0 8 0 3 4 1	11/82	EP			
	2 0 9 1 0 9 7	11/81	GB			
	0 1 7 0 7 5 2	12/84	EP			
	0 0 1 3 5 6 6	01/90	EP			
	0 1 0 8 2 9 5	10/83	EP			
	8 7 0 2 2 4 0	09/86	WO			
	9 3 1 2 7 7 2	12/92	WO			
	0 3 9 1 5 1 8	02/90	EP			
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	Walan, A. Et al. 1989 "Effect of omeprazole and ranitine on ulcer healing..." The N.E. J. Med 320:69.
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INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

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FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-Class	Translation Yes   No
	9 7 2 5 0 6 4	7-97	WIPO			
	0 4 2 6 4 7 9	5-90	EP			
	0 2 4 7 9 8 3	12-87	EP			
	0 3 6 5 9 4 7	5-90	EP			

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	Guess, H.A. et al. 1988 "Fatal upper gastrointestinal hemorrhage or perforation..." J. Clin. Epidimol 41:35-45
	Larkai, E.N. et al. 1987 "Gastroduodenal mucosa and dyspeptic symptoms..." Am. J. Gastroenterology 82:1153
	Catford, J.C. et al. 1986 "Confidential inquiry into deaths from peptic ulcer..." Health Trends 18:37-41
	Hawkey C. "Non-steroidal anti-inflammatory drugs and peptic ulcers..." (1990) 300:278-284
	Scheiman, J.M. "Pathogenesis of gastroduodenal injury..." (1982) Semin. Arthritis Rheum. 21(4):201-210-
	Walan, A. Et al. 1989 "Effect of omeprazole and ranitine on ulcer healing..." The N.E. J. Med 320:69.

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		5	8	1	7	3	3	8	06.10.98	Bergstrand et al.	424	474	
		5	7	6	3	4	2	2	09.07.98	Lichtenberger et al	514	78	12.05.95
		5	9	5	5	4	5	1	21.09.99	Lichtenberger et al	514	78	24.09.96

### FOREIGN PATENT DOCUMENTS

		Document No.							Date	Country	Class	Sub-Class	Translation Yes   No	
		9	8	2	2	1	1	7	28.05.98	WO				
		9	8	2	2	1	1	8	28.05.98	WO				

### OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

		Drug Facts and Comparisons 1994, pages 1679-1684
		Remington: The Science and Practice of Pharmacy, chapter 93, 1650-1656, 1995
		Wan, L.S.C., "A Multiple-unit Tablet Formulation for Multi-layer Drug-coated Granules", S.T.P. PHARMA SCIENCES, 4(5)(1994), PP-336-342.

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	Applicant: Depui et al.	
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	6 3 6 5 1 8 4	4/2002	DePui, et al.			

### FOREIGN PATENT DOCUMENTS

Document No.	Date	Country	Class	Sub-Class	Translation Yes   No
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9 5 0 9 8 3 1	13 Apr. 1995	WO			
9 5 3 0 6 4 1	16 Nov. 1995	WO			
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Chem. Pharm. Bull., 42(11), 2327-2331 (1994)
Chem. Pharm. Bull., 44(7), 1361-1366 (1996)

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